

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: May 10, 2017

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RETA ERXLEBEN,

Petitioner,

v.

SECRETARY OF HEALTH
AND HUMAN SERVICES,

Respondent.

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No. 14-385V

Special Master Gowen

Influenza (“Flu”) Vaccine;
Dysphagia; Vocal Cord Dysfunction;
Failure to Obtain Expert Report;
Dismissal for Insufficient Proof.

Edward M. Kraus, Law Offices of Chicago Kent, Chicago, IL, for petitioner.

Sarah C. Duncan, U.S. Dept. of Justice, Washington, DC, for respondent.

DECISION¹

On May 4, 2014, Reta Erxleben (“petitioner”) filed a petition pursuant to the National Vaccine Injury Compensation Program.² Petition, ECF No. 1. Petitioner alleged that she suffered from dysphagia, vocal cord dysfunction, and laryngeal dystonia caused-in-fact by an influenza (“flu”) vaccine administered on September 14, 2011. Petition at Preamble. As discussed below, petitioner has not been able to obtain a medical opinion supporting her claim. Therefore, this case is dismissed for insufficient proof.

I. Background

On May 4, 2014, petitioner filed her claim in the Vaccine Program. During the initial status conference on June 9, 2014, the undersigned directed petitioner to file outstanding medical

¹ Because this decision contains a reasoned explanation for the undersigned’s action in this case, the undersigned intends to post this ruling on the website of the United States Court of Federal Claims, in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). As provided by Vaccine Rule 18(b), each party has 14 days within which to request redaction “of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy.” Vaccine Rule 18(b).

² The Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-10 *et seq.* (hereinafter “Vaccine Act” or “the Act”). Hereafter, individual section references will be to 42 U.S.C. § 300aa of the Act.

records and to subsequently file an expert report opining that the flu vaccine was the cause in fact of petitioner's condition, under Althen v. Sec'y of Health & Human Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2008). Order, filed June 13, 2014 (ECF No. 5). Petitioner secured an expert and filed her two reports. Petitioner's Exhibit 56, filed January 14, 2015 (ECF No. 17); Petitioner's Exhibit 58, filed July 9, 2015 (ECF No. 25). Respondent filed a Rule 4(c) report recommending against compensation, as well as two responsive expert reports. Rule 4(c) report, filed April 15, 2015; Respondent's Exhibit A, filed April 15, 2015 (ECF No. 22); Respondent's Exhibit C, filed December 7, 2015 (ECF No. 34).

During a status conference on January 6, 2016, the undersigned ordered petitioner to have her expert review the additional medical records and to file another report no later than March 7, 2016. Order, filed January 6, 2016 (ECF No. 36). The undersigned scheduled an entitlement hearing to take place on March 9, 2017 and March 10, 2017. Hearing Order, filed February 9, 2016 (ECF No. 38).

At petitioner's request, the undersigned held a status conference on November 22, 2016. Order, filed November 22, 2016 (ECF No. 44). Petitioner reported that her expert was no longer available to support the claim. Id. Accordingly, the undersigned cancelled the hearing scheduled for March 2017. Id. Petitioner's counsel advised that he had already contacted another expert about possibly supporting petitioner's claim. Id. The undersigned directed petitioner to file a status report on this expert's decision no later than December 15, 2016. Id. Petitioner subsequently advised that the second expert was unable to offer an opinion in this case. Status Report, filed December 15, 2016 (ECF No. 45).

During a status conference on January 19, 2017, petitioner's counsel stated that he was continuing to seek another expert. Order, filed January 23, 2017 (ECF No. 47). On February 9, 2017, petitioner's counsel indicated that he had not been successful and requested another status conference to discuss how to proceed in light of these circumstances. Status Report, filed February 9, 2017 (ECF No. 48).

Petitioner then filed a report from Dr. Marcel Kinsbourne. Petitioner's Exhibit 75, filed March 28, 2017 (ECF No. 49). In his report, Dr. Kinsbourne offered a diagnosis of paradoxical vocal cord motion disorder ("PVCMD"). Id. at 1. He opined that the mechanism of PVCMD is uncertain. Id. at 2. However, his "extensive search" of the literature on this disorder "failed to reveal any indication that a vaccination could provoke its onset, or any mechanism by which it might do so. Specifically, there is no suggestion that PVCMD might be immune-mediated." Id.

On March 30, 2017, the undersigned held a status conference with petitioner, petitioner's counsel, and respondent's counsel. Order to Show Cause, filed March 31, 2017 (ECF No. 50). The undersigned stated that he did not believe that petitioner will be able to demonstrate that her condition was caused by the flu vaccine. While petitioner's condition developed in close temporal proximity to the vaccine, timing alone is not sufficient to show entitlement. To prevail, petitioner would need to submit a medical opinion or medical literature supporting that the vaccine actually caused her condition. The undersigned that in 2015, petitioner filed two reports from an expert who then withdrew from the case. Petitioner's counsel diligently attempted to secure a supportive opinion from another expert. Petitioner's counsel was only able to secure an

opinion from Dr. Kinsbourne, who wrote there was no evidence that PVCMM can be caused by a vaccine or is immune-mediated. Petitioner's counsel had also indicated that he would seek leave to withdraw from the case. Following this discussion, petitioner expressed a desire to attempt to seek an expert on her own. The undersigned granted petitioner an additional thirty days, until May 1, 2017, to attempt to locate an expert and supportive medical literature. The undersigned advised petitioner that if an expert is not located in that time, her case would be dismissed for insufficient proof.

On April 24, 2017, petitioner filed additional records of treatment by an otolaryngologist and a primary care physician. ECF No. 51. On April 26, 2017, petitioner filed a response, which she wrote herself, to the Order to Show Cause. ECF No. 52. The response addressed one aspect of respondent's Rule 4(c) report. It also detailed petitioner's health before the flu vaccine, her allergies, her research on the flu vaccine she received, and her theories of how the flu vaccine might have caused her condition, and her current condition. To date, petitioner has not filed an expert report or any medical literature in support of her claim, or indicate that she has made any progress towards doing so.

II. Analysis

To receive compensation under the Vaccine Act, a petitioner must prove either that (1) she suffered a "Table injury" – i.e., she suffered a specified injury within a specified period of time following the administration of a specified vaccine listed on the Vaccine Injury Table or (2) that her injuries were actually caused by a vaccine listed on the Table. §§ 300aa-13(a)(1)(A); §§ 300aa-11(c)(1). The records do not suggest, and petitioner does not contend, that she suffered a Table injury. Thus, she is necessarily pursuing a causation-in-fact claim. She has the burden of presenting (1) a medical theory; (2) a logical sequence of cause and effect; and (3) a medically acceptable temporal relationship between the vaccination and the injury. Althen, 418 F.3d at 1278 (Fed. Cir. 2008).

Under the Vaccine Act, a petitioner may not be found eligible to receive compensation based solely on her own claims. § 300aa-13(a)(1). Rather, the petition must be supported by either medical records or by medical opinion. § 300aa-13(a)(1).

In this case, because the medical records do not support petitioner's claim, she must file a medical opinion – either in the form of an expert report or medical literature. Petitioner was first informed of this burden during the initial status conference on June 9, 2014. Petitioner's injury is not often, if ever, seen in the Program. Petitioner did initially obtain an expert, who withdrew from the case in November 2016. For the next four months, petitioner's counsel - who has significant experience in the Vaccine Program – diligently attempted to find another expert. Counsel managed to obtain an opinion from Dr. Kinsbourne, an expert neurologist who has testified in support of other petitioners' claims in the Vaccine Program and is aware of its requirements. However, Dr. Kinsbourne ultimately could not offer an opinion in support of petitioner's claim. After fully reviewing the record and holding a status conference with petitioner, I granted her an additional thirty days to pursue a supportive expert opinion and medical literature. To date, petitioner has not filed an expert report or given any indication that she will be able to do so. Instead of filing the required medical opinion, petitioner filed her own

theory of the case. I sympathize with petitioner and appreciate the detailed history she has provided. However, it is not sufficient to establish causation. It is not from a medical expert, which in the case of this very unusual injury, would be particularly necessary. In fact, the most recent expert report that petitioner's counsel was able to obtain found no evidence of a causal relationship between the vaccine and petitioner's condition. Petitioner's self-written response details the chronology, but does not and could not address the first two Althen prongs, i.e., a medically and scientific theory as to how the vaccine could cause the injury, and a logical explanation of how it did. Petitioner's self-written response only presents a temporal association between the vaccine and the onset of her symptoms. However, timing cannot stand on its own without a theory. In summary, there is insufficient evidence to support petitioner's claim.³

III. Conclusion

Petitioner's claim is DISMISSED for insufficient proof. The Clerk SHALL ENTER JUDGMENT accordingly.

IT IS SO ORDERED.

s/Thomas L. Gowen

Thomas L. Gowen
Special Master

³ Counsel also seems to recognize the difficulties with petitioner's claim. Her current counsel filed petitioner's claim in May 2014. After working diligently on her behalf for almost three years, in March 2017, he stated his intention to withdraw from the case. However, petitioner has not managed to obtain substitute counsel.